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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,685	10/06/2005	Heinz Winkler	WBW-13116	8378

24131 7590 04/25/2008
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EXAMINER	
FORD, ALLISON M	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
04/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,685	WINKLER, HEINZ	
	Examiner	Art Unit	
	ALLISON M. FORD	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-38* is/are pending in the application.

4a) Of the above claim(s) *25-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20050705*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 13-24, in the reply filed on 02/07/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 13-38 remain pending in the current application, of which claims 25-38 have been withdrawn from consideration as being directed to non-elected subject matter. Claims 13-24 have been considered on the merits.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 371, which papers have been placed of record in the file. The instant application is a national stage entry of PCT/AT03/00362, filed 12/05/2003. Additionally, acknowledgment is made of applicant's claim for foreign priority under 35 USC 119(a)-(d) to Austrian application 1825/2002, filed 12/05/2002. A certified copy of the foreign priority document has been received and placed in the application file.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is considered indefinite because it is not clear if the claimed implant material includes "a tissue cell suspension for regeneration", or if the infiltration channels must only be configured to be able to receive such a suspension.

Furthermore, in claims 13 and 15, the phrase "tissue cell suspension" is unclear. A tissue is an aggregate of interconnected cells with intracellular connections, *i.e.* not a suspension of cells. Clarification is required.

Claims 18 and 20 are considered indefinite because it is not clear what parameter the "value" is referencing: "a value of said depth is approximately 5-fold to 10-fold a value of said diameter".

Claim 19 is considered indefinite because frustums, by definition, are not pointed, but end in a flat surface; therefore the term 'pointed frustum' is indefinite. (From the Merriam-Webster Online Dictionary: **Frustum:** the basal part of a solid cone or pyramid formed by cutting off the top by a plane parallel to the base; http://www.merriam-webster.com/dictionary/frustum, accessed 04/21/2008).

Claim 24 lacks antecedent basis for the limitation "the part of said supporting body impregnated with cartilage cell suspension" in the 1st-2nd lines of the claims. Claim 14 does not recite such a part. It appears claim 24 should depend from claim 15, which requires the implant of claim 13 to be impregnated with a cartilage tissue cell suspension; however, even claim 15 fails to recite "a part" of the supporting body to be impregnated, therefore antecedent basis is still absent. For purposes of applying art, claim 24 is being interpreted as depending from claim 15, which requires the presence of a cartilage cell suspension.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13, 14 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Beam et al (US 2003/0065400).

Beam et al disclose an engineered regenerative biostructure (ERB) which useful as a bone implant material.

The ERB exhibits a microporosity between packed granules, and it further has an engineered internal architecture, which may include micro-, meso- and/or macroporosity in the form of interconnected channels and/or pores (See Beam et al, at least paragraphs 0041, 0045-0046 & 0054-0057). Various substances may be infused into the engineered internal architecture (See Beam et al, paragraphs 0041 & 0192). The ERB may be comprised of a ceramic material, hydroxyapatite, polymers and/or demineralized bone matrix (See Beam et al, paragraph 0041 & 0046), each of which are considered 'body-tolerable materials'.

The ERB of Beam et al is considered to read on the instantly claimed implant material, as the ERB is considered to be a supporting body of a body-tolerable material which has a porous structure; furthermore, the engineered internal architecture, comprising micro-, meso-, and macroporosity, of the ERB is considered to read on infiltration channels which are capable of receiving a cell suspension therewithin for regeneration of bony tissue upon implantation (claim 13). When the ERB comprises demineralized bone matrix, the 'supporting body' of the ERB comprises material obtained from spongy bone (claim 14).

The shape of the ERB may be manipulated to fit the defect. Figure 2A shows an ERB (200) having a cylindrical shape, having a base and a top (which applicants call a 'cover surface'), wherein at

least some of the infiltrating channels (220) start at the base of the ERB (See Beam et al, paragraph 0047 & Fig. 2A) (claim 22).

Therefore the reference anticipates the claimed subject matter.

Claims 13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Mears (US Patent 4,553,272).

Mears discloses an implant material for regeneration of human or animal tissue, including joints, comprising a porous implant member with a cell solution impregnated therewithin (See Mears, col. 2, ln 15-39). The porous implant member may be comprised of titanium, stainless steel, polyethylene, or other polymers (See Mears, col. 3, ln 45-54), each of which are considered 'body-tolerable materials'. Cartilage cells may be impregnated into the porous implant member (See Mears, col. 2, ln 30-39).

The implant material of Mears is considered to read on the instantly claimed implant material, with the porous implant member being the supporting body of a body-tolerable material having a porous structure, and having pores (which read on channels) beginning from the external surface, and ending in the interior of the implant member, the pores (channels) are capable of receiving a cell suspension material.

Therefore the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13, 14 and 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beam et al (US 2003/0065400).

The teachings of Beam et al are set forth above; Beam et al has been shown to anticipate claims 13, 14 and 22. Generally Beam et al disclose an engineered regenerative biostructure (ERB) which useful as a bone implant material; the ERB is made of 'body-tolerable materials'. The ERB exhibits a microporosity between packed granules, and it further has an engineered internal architecture, which may include micro-, meso- and/or macroporosity in the form of interconnected channels and/or pores (See Beam et al, at least paragraphs 0041, 0045-0046 & 0054-0057).

Beam et al differs from the instant invention in that they do not disclose the exact same shapes, sizes and orientations of the engineered internal architecture (considered to read on the infiltrating channels of the instant invention), nor do they disclose the ERB body to exhibit a cylindrical shape with one end having a convex shape. However, because the differences between Beam et al and the instant invention are limited to differences in size and shape, and Beam et al discloses the size and shape of both the internal architecture and the shape of the ERB body can each be manipulated to suit the individual design needs, the instant invention is considered to be *prima facie* obvious over Beam et al. It has been held that in situations where the only difference between the prior art and the claimed invention is a difference in shape or size, and the prior art discloses means for modifying the shape and/or size of their product in order to suit a design need, and there is otherwise no persuasive evidence that the claimed configuration was significant or that a device having the claimed relative dimensions would perform differently than the prior art device, the claimed product is not patentably distinct from the prior art product. See *In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966),* and *In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984),cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).*

With regards to the dimensions of the engineered internal architecture (including the channels and pores), Beam et al disclose the micro-, meso- and/or macroporosity may be designed to form a predetermined pattern (See Beam et al, paragraphs 0054-0057 & 0073-0090, particularly 0083). Particularly with regards to 'macrochannels', Beam et al disclose the channels may have a dimension of 2 to 2000 microns, preferably from 200-700 microns (See Beam et al, paragraph 0056). Please note this range substantially overlaps that claimed (200-500 microns), it has been held that when the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)*. The channels may be long in comparison to their width and/or depth. Beam et al further discloses the cross-section of the channels may be constant, or alternatively may be variable, thereby suggesting infiltrating macrochannels that start from the surface of the supporting body and taper inwardly, such as to a pointed cone shape or to a pointed frustum shape. Therefore, the size, shape and orientation of the infiltrating macrochannels in the ERB of Beam et al are considered to render obvious the infiltrating channels currently claimed (claims 16-21).

With regards to the shape of the ERB, Beam et al disclose the shape of the ERB may be manipulated to fit the defect. Figure 2A shows an ERB (200) having a cylindrical shape, having a base and a top (which applicants call a 'cover surface'), wherein at least some of the infiltrating channels (220) start at the base of the ERB (See Beam et al, paragraph 0047 & Fig. 2A). Figure 2A does not show the ERB to have a convex top (cover surface); however, because the shape of the ERB can be designed to specifically fit an anatomical defect (See Beam et al, paragraph 0047), manipulation of the ERB to have any desired shape, including that described in claim 23, would have been *prima facie* obvious to one of ordinary skill in the art (claim 23).

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 13-15, 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beam et al (US 2003/0065400), in view of Mears (US Patent 4,553,272).

The teachings of Beam et al are set forth above; Beam et al has been shown to anticipate claims 13, 14 and 22. Generally Beam et al disclose an engineered regenerative biostructure (ERB) which useful as a bone implant material; the ERB is made of 'body-tolerable materials'. The ERB exhibits a microporosity between packed granules, and it further has an engineered internal architecture, which may include micro-, meso- and/or macroporosity in the form of interconnected channels and/or pores (See Beam et al, at least paragraphs 0041, 0045-0046 & 0054-0057).

Beam et al differs from the instant invention in that, while they state various substances may be infused into the engineered internal architecture (See Beam et al, paragraphs 0041 & 0192), they do not specifically disclose a cartilage cell suspension as such a material.

Mears discloses producing an implant material for regeneration of bony tissue, including joints, comprising introducing cartilage cells into a porous implant material (See Mears, col. 2, ln 15-39). Mears states the presence of cells within the porous implant advantageously aids in regeneration of natural tissue upon implantation (See Mears col. 4, ln 65-col. 5, ln 6).

Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to apply a cartilage cell suspension (as disclosed by Mears) to the ERB of Beam et al (claims 15, 24). One of ordinary skill would have been motivated to apply a cartilage cell suspension to the ERB of Beam et al in order to induce growth of cartilage cells (chondrocytes) within the ERB so that, upon implantation, the implant material will have a greater probability of successfully incorporating as a natural tissue structure. One would have had a reasonable expectation of successfully applying a cartilage

cell suspension to the ERB of Beam et al because Beam et al state various substances and biologic agents can be imbibed into the porous ERB, and Mears provides teachings on how to produce a cartilage cell suspension, and how to seed such a cell suspension onto porous implant materials. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford Jr/
Primary Examiner, Art Unit 1651